IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:	Confirmation No.: 1018
Bradford J. DUFT et al.	Art Unit: 1645
Appl. No.: 09/445,517	Examiner: Sarvamangala J.N. DEVI
Filed: December 6, 1999	Atty. Dkt. No. 235/013US
For: METHODS FOR TREATING OBESITY	

Response to Notification of Non-Compliant Apppeal Brief and

Brief on Appeal

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

In response to the Notification of Non-Compliant Apppeal Brief, mailed October 20, 2008, for the above-identified application, Applicants (herein, "Appellants") hereby appeal under 37 C.F.R. § 41.37 the Final Rejection of Claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, 80, 82, 84 and 95-97 (Final Office Action, mailed February 11, 2008; Advisory Action, mailed May 28, 2008). This Appeal Brief follows a Notice of Appeal filed May 12, 2008, and the filing of an allegedly non-compliant Appeal Brief August 7, 2008.

The requisite fee for an Appeal Brief was paid with the submission dated August 7, 2008, at which time a petition for extension of time under 37 C.F.R. § 1.136 and fee under 37 C.F.R. § 1.17 for one-month was submitted. Accordingly, Appellants believe that no additional fee is due for the present submission. However, the Commissioner is hereby authorized to charge payment for any outstanding fee set forth for this Appeal Brief to Applicants' Deposit Account No. 010535, referencing Atty. Dkt. No. 235/013 US.

CERTIFICATE OF TRANSMITTAL UNDER 37 C.F.R. 1.8

I hereby certify that this paper (along with anything referred to as being attached or enclosed) is being electronically filed via EFS-Web at the United States Patent and Trademark Office, on the date shown below.

October 29, 2008
Date of Deposit

Debra A. Villanueva
Name of Person Filing Paper

Signature of Person Filing Paper

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Real Party of Interest

The real party of interest is Amylin Pharmaceuticals, Inc. a Delaware corporation with offices at 9360 Towne Centre Drive, San Diego, California 92121.

Related Appeals and Interferences

An appeal is pending in related U.S. Appl. No. 08/870,762, filed June 6, 1997, from which the instant application is a continuation-in-part.

Status of Claims

Claims 23-29, 31-39, 68-80, 82 and 84-97 are pending, with Claims 25-26, 28, 35-36, 69-71, 73-75, 77-79 and 85-94 withdrawn, and with Claims 1-22, 30, 40-67, 81 and 83 cancelled. Claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, 80, 82, 84 and 95-97 are under appeal.

Status of Amendments

All amendments in the instant application have been entered. In particular, the after-final amendment filed May 12, 2008, in response to the Final Office Action mailed February 11, 2008, has been entered.

Summary of Claimed Subject Matter

Independent Claims 23, 33 and 76 relate to methods of treating obesity. As described in the specification, it has been surprisingly discovered that amylin as well as amylin agonists can be used for treatment of obesity in humans. See, *e.g.*, specification page 12, lines 5-9.

1. Independent Claim 23

Independent Claim 23 is directed to a method of treating obesity in a human subject comprising administering to the subject an amount of a composition comprising an amylin or amylin agonist effective to treat obesity in the human subject, wherein the amount of the amylin or amylin agonist administered in the composition is about 0.01 mg to about 5 mg per day, wherein the composition is not administered in conjunction with another obesity relief agent, and wherein the human subject is in need of treatment for obesity. Support for Claim 23 may be found throughout the specification, at e.g., page 12, lines 10-26; page 27, lines 20-29.

2. Dependent Claim 24

Dependent Claim 24, dependent on Claim 23, further requires that the amylin agonist of

Claim 23 is an amylin agonist analogue, support for which may be found in the specification at, e.g., page 13, lines 9-10.

3. Independent Claim 33

Independent Claim 23 is directed to a method of treating obesity in a human subject consisting of administering to the subject an amount of a composition effective to treat obesity in the human subject, the composition comprising an obesity relief agent consisting of an amylin or an amylin agonist and a pharmaceutically acceptable carrier, wherein the amount of the amylin or amylin agonist administered in the composition is about 0.01 mg to about 5 mg per day, and wherein the human subject is in need of treatment for obesity, rupport for which may be found throughout the specification, at e.g., page 12, lines 10-26 and lines 24-26; page 27, lines 20-29.

4. Dependent Claim 34

Dependent Claim 34, dependent on Claim 33, further requires that the amylin agonist of Claim 33 is an amylin agonist analogue, support for which may be found in the specification at, e.g., page 13, lines 9-10.

5. Dependent Claim 68

Dependent Claim 68, dependent on Claim 24, further requires that the amylin agonist analogue of Claim 24 has a defined structure which is provided, support for which may be found in the specification at, e.g., page 15, all lines.

6. Dependent Claim 72

Dependent Claim 72, dependent on Claim 34, further requires that the amylin agonist analogue of Claim 34 has a defined structure which is provided, support for which may be found in the specification at, e.g., page 15, all lines.

7. Independent Claim 76

Independent Claim 76 is directed to a method of treating obesity in a human subject comprising administering to the subject an amount of a composition effective to treat obesity in the human subject, wherein the human subject is in need of treatment for obesity, the composition comprising a peptide having a defined sequence which is provided, support for which may be found in the specification at, e.g., page 12, lines 10-26; page 15, all lines.

8. Dependent Claim 80

Dependent Claim 80, dependent on Claim 23, further requires that the amylin or agonist thereof of Claim 23 is administered from about 30 μg/dose to about 300 μg/dose, support for which may be found in the specificatiobn at, e.g.,.page 28, line 8 and Claim 6 as filed.

Grounds of Rejection to be Reviewed on Appeal

1. Whether Claims 23, 24, 33 and 34 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 34 and 35 of Gaeta *et al.* (U.S. Patent No. 5,686,411) (hereinafter "Gaeta," already of record) as evidenced by Tsanev (*Vutr. Boles* **23**:12-17, 1984, hereinafter "Tsanev," already of record).

2. Whether Claims 23 and 33 are unpatentable under the judicially created doctrine of obviousness-type double patenting over claims 11 and 13 of Beaumont *et al.* (U.S. Patent No. 5,321,008) (hereinafter "Beaumont," already of record) as evidenced by Tsanev and Rink *et al.* (U.S. Patent No. 5,739,106) (hereinafter "Rink," already of record).

3. Whether Claim 33 and Claims 34, 37-39, 72, 80, 82 and 96 dependent therefrom are unpatentable under 35 U.S.C. § 112, first paragraph, as containing new matter.

4. Whether Claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, 80, 82, 84 and 95-97 are unpatentable under 35 U.S.C. § 112, first paragraph, as being non-enabling with regard to the scope of the claims.

5. Whether claims 23-24, 27, 29, 31, 33, 34, 37-39, 80 and 82 are unpatentable under 35 U.S.C. § 102(b) as anticipated over Kolterman *et al.* (WO 96/40220) (hereinafter "Kolterman '220," already of record) as evidenced by Tsanev.

6. Whether Claims 23, 24, 29, 33, 34 and 38 are unpatentable under 35 U.S.C. §102(e)(2) as anticipated over Gaeta as evidenced by Tsanev.

7. Whether Claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and 82 are unpatentable under 35 U.S.C. § 102(b) as being anticipated by Kolterman et al. (*Diabetologia* **39**:492-499, April 1996) (hereinafter "Kolterman 1996," already of record) as evidenced by Itasaka *et al.* (*Psychiatr. Clin. Neurosci.* **54**:340-341, June 2000) (hereinafter "Itasaka," already of record).

8. Whether Claims 23, 24, 27, 29, 33, 34, 37 and 38 are unpatentable under 35 U.S.C. § 102(e)(2) as being anticipated by Beaumont as evidenced by Tsanev.

Argument

1. Claims 23, 24, 33 and 34 are not obvious under the judicially created doctrine of obviousness-type double patenting over Gaeta as evidenced by Tsanev.

The rejection of Claims 23, 24, 33 and 34 (Final Office Action, page 5, item 21) under the judicially created doctrine of obviousness-type double patenting over claims 34 and 35 of Gaeta as evidenced by Tsanev is in error for reasons of record and reasons provided herewith.

Initially, the current Rejection 1, and the following Rejection 2, are obviousness-type double patenting rejections. The predecessor court to the Federal Circuit has held that

> [t]he inherency of an advantage and its obviousness are entirely different questions. That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown. *In re Shetty*, 566 F.2d 81, 86, 195 U.S.P.Q. 753, 756-57 (C.C.P.A 1977) (quoting *In re Spormann*, 363 F.2d 444, 448, 150 U.S.P.Q. 449, 452 (C.C.P.A. 1966)).

Accordingly, all Examiner arguments invoking inherency of alleged evidence (e.g., Tsanev and/or Rink) in Rejections 1-2 are properly viewed consistent with *In re Shetty*, wherein the alleged specific property must be known in order to be deemed inherent.

Claims 23, 24, 33 and 34 are not-obvious over the references

The rejected claims are not obvious over the alleged prior art at least becasue the alleged prior art does not include all of the elements of the instant claims as required by the law. In particular, the references provide no guidance concerning the identification of or intent to treat a subject in need of treatment for obesity. Accordingly, the instant claims are patentably distinct over the reference claims.

Specifically, Claims 23, 24, 33 and 34 are generally directed to the treatment of obesity in a human in need of treatment thereof. In contrast, as acknowledged by the Examiner (Final Office Action, page 5, last paragraph), claims 34 and 35 of Gaeta are merely directed to methods for the treatment of diabetes mellitus in a mammal comprising the administration of a therapeutically effective amount of a particular amylin agonist analogue. In particular, Gaeta is silent with respect to the treatment of obesity. Indeed, Gaeta makes no disclosure whatsoever that amylin or agonist thereof is effective in the treatment of obesity.

In an attempt to cure the deficiency of Claims 34 and 35 of Gaeta, the Examiner relies on Tsanev to assert that 80-90% of diabetic patients are obese. In view of the disclosure of Tsanev, the Examiner asserts (Final Office Action, page 6, lines 10-16) that

> [g]iven the art-known prevalence of intrinsic obesity in 80% to 90% of diabetic patients as disclosed by Tsanev, at least one of the human diabetic patients used in the method disclosed in the '411 patent qualified as a human patient in need of treatment for obesity. Therefore, the method of the '411 patent comprising or consisting of the administration of 0.1 to 5 mg, or 0.5 to 1.0 mg of the amylin agonist, ^{25,28,29}Pro-human amylin alone or in conjunction with insulin or glucagon, to a diabetic human anticipates the instant claims (*emphasis added*).

Even in view of Tsanev, a claim to treating diabetes mellitus with an amylin agonist analogue (i.e., claims of Gaeta) does not teach or suggest treating subjects as currently claimed. Furthermore, nothing in the cited claims teaches or suggests the identification of, or intent to treat, a subject in need of treatment for obesity. The courts have held that the phrase "in need thereof" (e.g., as recited in independent Claims 23 and 33) is meaningful, and that "the claims' recitation of a patient or a human 'in need' gives life and meaning to the preambles' statement of purpose." *Jansen v. Rexall Sundown, Inc.* 342 F.3d 1329, 1333 (Fed. Cir. 2003). Thus, since the cited claims do not teach or suggest treating obesity, the intent to treat human subjects in need of treatment for obesity, or the use of an amount effective to treat obesity, a skilled artisan would have no expectation of success for the claimed invention in view of the cited claims, because Gaeta is silent with respect to treating obesity. In this regard, "[r]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness." *KSR Int'l Co. v. Teleflex Inc.,* 127 S.Ct. a1727, 1741, 2007, quoting *In re Kahn* 441 F.3d 977, 988 (Fed. Cir. 2006) (emphasis added). Indeed, the prior art must still suggest a predictable outcome to establish a *prima facie* case of obviousness. See, *e.g.*, *Takeda Chemical Industries, Ltd v. Alphapharm Pty., Ltd.* 492 F.3d 1350, 83 U.S.P.Q.2d 1169 (Fed. Cir. 2007).

Furthermore, the Examiner improperly asserts inherent anticipation in view of Tsanev (Final Office Action, page 6, lines 18-19): "the method of the '411 patent is expected to bring about obesity-treating effect ... (*emphasis added*)". Appellants reiterate that current Rejection 1, as well as following Rejection 2, is for obviousness-type double patenting. Thus, the Examiner's reliance on inherency in the context of anticipation in the rejections is contrary to the law. See *In*

re Shetty,(Id.)

Nonetheless, in response to the Examiner's assertion, anticipation based on inherency in any event is appropriate only when the prior art relied upon necessarily includes all of the elements of the claims in question and is the natural result of following the instructions or examples of the prior art. See, *Atofina v. Great Lakes Chemical Corp.*, 441 F.3d 991, 78 USPQ2d 1417, 1424 (Fed. Cir. 2006); *SmithKline Beecham Corp. v. Apotex Corp.,* 403 F.3d 1331, 1334, 74 USPQ2d 1398, 1407 (Fed. Cir. 2005) (citing *Schering Corp. v. Geneva Pharms., Inc.*, 339 F. 3d 1373, 1377, 67 USPQ2d 1664, 1667 (Fed. Cir. 2003)). The Court in *Schering* relied in part on the decision *In re Cruciferous Sprouts Litigation,* 301 F.3d 1343, 1351, 64 USPQ2d 1202, 1206 (Fed. Cir. 2002) wherein it was noted that to demonstrate inherency, it was necessary to show that the prior art necessarily, always functions in accordance with the claims addressed. The requirement that the teaching of a reference always, under any circumstances, necessarily satisfies the recitation of the claims to make out a case of inherent anticipation was reaffirmed by the Federal Circuit in *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, 471 F.3d 1363, 1368 (Fed. Cir. 2006). It is well settled that a determination of inherency cannot be established by probabilities or possibilities, but that it is incumbent upon the Examiner to establish the inevitability of the inherency which is propounded. *In re Oelrich*, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981); *In re Wilding*, 535 F.2d 631, 635-36, 190 USPQ 59, 63-64 (CCPA 1976).

However, Tsanev discloses that 80-90% of diabetic patients are obese, which falls short of the 100% (i.e., always, under any circumstances) criterion required by the present claims and required by the law. Accordingly, Claims 34 and 35 of Gaeta support neither *prima facie* obviousness nor anticipation with regard to the claimed invention.

Furthermore, the Examiner improperly asserts (Advisory Action, page 6, lines 8-18) that the prior art method necessarily includes all of the elements of the instant claims as evidenced by Thompson et al (*Diabetes* **46**: Suppl. 1, page 30A, 0116, 02 May 1997) (hereinafter "Thompson 1997," already of record). Thompson 1997 is unavailable as prior art for the instant application. Specifically, Appellants had filed a declaration under 37 C.F.R. §1.131 in the Response to Office Action dated December 3, 2002, which declaration demonstrates that the current application antedates Thompson 1997 and was inventors' own work. Acknowledgment of the declaration

was provided by the Examiner in the Non-final Office Action dated May 30, 2006, at which time the filing date of the instant application (December 6, 1999) was accorded to Claims 23, 32-34 and 76 due to alleged new matter in these claims with respect to the parent U.S. Patent Application No. 08/870,762, filed June 6, 1997 (hereinafter the "'762 application," already of record). The alleged new matter rejections were subsequently withdrawn for Claims 23, 32-34 and 76, as acknowledged by the Examiner (Non-final Office Action dated April 23, 2007, paragraph items 18-20). Furthermore, support for the subject matter of currently rejected claims 23, 24, 33 and 34 may be found in the specification for the parent '762 application at e.g., page 9, lines 6-18 and lines 24-26; page 23, lines 4-6. Thus, instant Claims 23, 24, 33 and 34 antedate Thompson 1997. Accordingly, Thompson 1997 is unavailable as prior art against the current application. The Examiner appears to require Thompson 1997 in order to demonstrate a nexus between administration of an amylin or agonist thereof and treatment for obesity. However, Appellants invention was made prior to Thompson 1997, which is not available to supply the necessary connection between amylin or agonist thereof and treatment for obesity. Thus, the Examiner has failed to provide evidence or argument with any rational underpinning that the current claims are obvious in view of Gaeta as evidenced by Tsanev. Whatever else is taught by Gaeta and Tsanev, the references do not teach or suggest a method of treating obesity in a subject in need of treatment thereof. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the obviousness-type double patenting rejection.

2. Claims 23 and 33 are not obvious under the judicially created doctrine of obviousness-type double patenting over Beaumont as evidenced by Tsanev and Rink.

The rejection of Claims 23 and 33 (Final Office Action, page 6, item 22) under the judicially created doctrine of obviousness-type double patenting over claims 11 and 13 of Beaumont, as allegedly evidenced by Tsanev and Rink is in error for reasons of record and for the following reasons.

Claims 23 and 33 are non-obvious over the references

Arguments set forth for Rejection 1 are reiterated. Additionally, the cited references, alone or in combination, do not include all of the elements required by the rejected claims. In particular, the references individually or collectively provide no guidance concerning the

identification of or intent to treat a subject in need of treatment for obesity. Furthermore, the Examiner's reliance on argument based on alleged inherency in the Tsanev and Rink disclosures is legally deficient because the current rejection is for obviousness-type double patenting, not anticipation. Accordingly, for at least these reasons the instant claims are patentably distinct over the reference claims.

Specifically, the subject matter of Claims 22 and 33 is discussed above. In contrast, Claim 11 of Beaumont is directed to a method for the treatment of diabetes mellitus in an insulin-requiring mammal (human) comprising administering a therapeutically effective amount of a calcitonin. Claim 13 of Beaumont is directed to the method of treatment of type II diabetes mellitus comprising the step of administering a therapeutically effective amount of an insulin and a calcitonin to achieve improved glycemic control over insulin therapy alone. However, the cited claims of Beaumont are silent with regard to treating obesity.

The Tsanev disclosure has been discussed in the argument to previous Rejection 1. The Rink disclosure merely contemplates amylin-induces appetite suppression in rodents. Indeed, the Rink patent does not describe the treatment of obesity in humans using amylin or an amylin agonist, or intention to treat a human subject in need of treatment, as required by the claims of the present invention.

In view of the similarity of the current rejection to Rejection 1 above, Appellants reiterate the arguments provided above relating to nonstatutory obviousness-type double patenting. In particular, similar to Rejection 1, the Examiner's attempts to cure the deficiencies of Beaumont by citing the alleged prevalence of intrinsic obesity (80-90% according to Tsanev) which falls short of the 100% required by the claims and required by the law in an anticipation rejection, and also falls short because Beaumont, whether evidenced by Tsanev or not, is silent with respect to the treatment of obesity and the identification of a subject population in need of treatment for obesity. Again, the Examiner has failed to demonstrate a nexus between administration of an amylin or agonist thereof and treatment for obesity in humans in need of treatment thereof. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the obviousness-type double patenting rejection.

3. Claim 33 and Claims 34, 37-39, 72, 80, 82 and 96 dependent therefrom contain no new matter under 35 U.S.C. § 112, first paragraph: new matter

The rejection of Claim 33 and dependent Claims 34, 37-39, 72, 80, 82 and 96 under 35 U.S.C. §112, first paragraph (Final Office Action, page 8, item 23), as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter rejection), is in error for the reasons of record and the following reasons. Initially, Claim 80 depends from Claim 23, not Claim 33. Accordingly, Appellants request that Claim 80 also be reviewed independently of the other dependent claims.

Claims 34, 37-39, 72, 82 and 96 contain no new matter

The present rejection relates to three phrases (Final Office Action, page 8, lines 8-10) in the claims: 'in said human subject,' 'wherein said human subject is in need of treatment for obesity,' and 'method of treating obesity .... consisting of administering.'

Regarding the phrase 'in said human subject,' the amendment was made in the Response to Office Action filed October 24, 2007, solely to define the claim with greater particularity, support for which may be found in the specification at, e.g., page 12, lines 5-9.. Indeed, the phrase was the suggestion of the Examiner (Office Action dated April 23, 2007, page 22, first paragraph) to overcome a rejection of Claim 33 under 35 U.S.C. § 112, second paragraph, which rejection was overcome as acknowledged by the Examiner (Final Office Action, page 4, item 14). Regarding the phrase 'and wherein said human subject is in need of treatment for obesity,' support for this phrase is found throughout the specification (at e.g., page 12, lines 24-26: "[t]reating obesity therefor includes the inhibition of weight gain and inducing weight loss in patients in need thereof (*emphasis added*).") Regarding the phrase, 'method of treating obesity .... consisting of administering,' ample support for this phrase is found throughout the specification, at e.g., Abstract (i.e., "... a therapeutically effective amount of an amylin or an amylin agonist alone or in conjunction with another obesity relief agent (*emphasis added*)"), or page 2, lines 9-12. Furthermore, in any event, the term "consisting" as used in Claim 33 is a term of art (transitional claim language) that need not be specifically recited in the specification.

Accordingly, Appellants request that the Board remand the application to the Examiner

with instructions to remove the current rejection.

Claim 80 contains no new matter

Arguments with respect to Claims 34, 37-39, 72, 82 and 96 are reiterated. Additionally, Claim 80 does not depend from Claim 33 as asserted in the rejection. Thus, the rejection of Claim 80 is defective. Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

4. Claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, 80, 82, 84 and 95-97 are enabled under 35 U.S.C. § 112, first paragraph: enablement

The rejection of Claims 23, 24, 27, 29, 31-34, 37-39, 68, 72, 76, 80, 82, 84 and 95-97 (Final Office Action, page 9, item 24) under 35 U.S.C. §112, first paragraph, as allegedly not enabling any person skilled in the art to use the invention commensurate in scope with the claims, is in error for the reasons of record and the following reasons. Appellants request the following grouping of claims: a) Claims 23, 24, 27, 29, 31-34, 37-39, 80, 82, 95 and 96; b) Claim 68; c) Claim 72; and d) Claims 76, 84 and 97.

Initially, the proper standard for determining compliance with the enablement requirement is whether the specification provides sufficient information to permit one skilled in the art to make and use the claimed invention. *United States v. Telectronics, Inc.*, 8 USPQ2d 1217, 1223 (Fed. Cir. 1988). The test of enablement is not whether experimentation is necessary, but rather whether any experimentation that is necessary is undue. A considerable amount of experimentation is permitted, provided that it is merely routine, or provided that the specification provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed. *In re Wands*, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988). A specification that discloses how to make and use a claimed invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented "must be taken as in compliance with the enabling requirement of the first paragraph of $ 112 unless there is reason to doubt the objective truth of the statements contained therein." *In re Brana*, 51 F.3d 1560, 1566, 34 U.S.P.Q.2d 1436, 1441 (Fed. Cir. 1995) (quoting *In re Marzocchi*, 439 F.2d 220, 223, 169 U.S.P.Q. 367, 369 (C.C.P.A. 1971) (emphasis in original)). With respect to reasons for doubting the objective truth of the specification, the Examiner asserts (Final Office

Action, page 15, lines 20-31) that Applicants' discussion in an Appeal Brief filed July 2000 for the parent application (U.S. Appl. No. 08/870,762) regarding U.S. 5,739,106 ("Rink") allegedly provides a reason for doubting the objective truth contained within the specification. However, when read in context, it is clear that Rink only contemplates amylin-induces appetite suppression in rodents and not in human subjects as required by the instant claims. Indeed, Rink does not describe the treatment of obesity in humans using amylin or an amylin agonist as required by the instant claims. Accordingly, the Examiner's reliance on Applicants' Appeal Brief filed July 2000 for the parent application regarding Rink is irrelevant.

It is well established that enablement does not require the inventor to submit an exact blueprint or recipe to practice the invention; thus, experimentation is allowed. *In re Angstadt*, 190 USPQ 214 (CCPA 1976). Rather, the determination of what constitutes undue experimentation relies on the Wands factors: (1) the quantity of experimentation necessary (time and expense); (2) the amount of direction or guidance presented; (3) presence of absence of a working example; (4) nature of the invention; (5) the state of the prior art; (6) the relative skills of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims. *In re Wands, Id.*

Claims 23, 24, 27, 29, 31-34, 37-39, 80, 82, 95 and 96 are enabled

An analysis of the Wands factors (*In re Wands, Id.*) for the rejected claims, and additional arguments related to all claims under the current rejection follow.

Regarding the quantity of experimentation necessary, the standard for determining enablement is whether the experimentation needed to practice the invention is undue or unreasonable. *Mineral Separation v. Hyde*, 242 U.S. 261, 270 (1916). In this respect, one of ordinary in the art would have the ability to select amylin and amylin agonist peptides for use in the claimed methods without undue experimentation in view of the specification.

Regarding the amount of direction or guidance presented, the specification broadly discloses that the claimed amylin compounds are useful in the treatment of obesity in a subject in need thereof. The specification and claims as filed further discloses amylin agonist analogues of the invention with great particularity. Furthermore, there is express guidance as to modes of administration, therapeutic dosages, mechanisms for assessing therapeutic efficacy, as well as a

working example to demonstrate the statistically significant ability of an exemplary amylin compound to treat obesity in a human subject in need thereof. In a working example, the human subjects were Type 2 diabetics. That the working example illustrated Type 2 diabetic subjects taking insulin does not render the scope of enablement limited to this subject population. Rather, it demonstrates that in a particularly difficult to treat, obese subject population (Type 2 diabetic subjects taking insulin), an exemplary amylin compound is therapeutically effective in the treatment of obesity. Moreover, taken together with the teachings of the specification, the working example provides a baseline approach for establishing therapeutic efficacy of exemplary amylin compounds within the context of the presently claimed methods. Utilizing similar study structures, Appellants have in fact established that exemplary amylin compounds are effective in the treatment of obesity in non-diabetic subjects as well (see, e.g., IDS entries AZ1, AZ2, AZ4 and AZ5 of Aronne, et *al. and* Smith, et *al.* of record). This evidence confirms the teachings of Appellants specification, and demonstrates that Appellants' working example in fact provides enablement of the efficacy of a particularly difficult to treat, chronically obese subject population.

The Examiner asserts (Final Office Action, page 16, lines 5-9 that "the instant specification fails to show that human or non-human amylin, or a composition comprising or consisting of the same, was in fact, soluble and/or non-aggregating enough to be 'therapeutic' in a method of treating obesity upon administration in any amount and by any route, with or without concurrent insulin therapy, to a diabetic or non-diabetic human subject in need of treatment for obesity." The Examiner is impermissibly attempting to limit the scope of enablement to the scope of Appellants' working examples. Based on the extensive guidance provided in the specification, including the human clinical study results, as well as the high level of skill in the art, the skilled artisan would be able to evaluate efficacy of amylin compounds in accordance with the methods of the inventions to ascertain therapeutically effective amounts of the recited amylin compounds. In fact, the Examiner's characterization of Example 1 only serves to underscore the enablement of the claims in this regard. For instance, Example 1 describes a clinical study wherein routine dosages were evaluated in human clinical subjects to ascertain a therapeutically effective dose as well as effective administration regimens.

Regarding the presence or absence of a working example, the working examples, in

combination with the disclosure of the specification and knowledge of one skilled in the art, amply enable the full scope of the invention as presently claimed.

Regarding the nature of the invention, the nature of the invention is pertinent to the treatment of obesity in a human subject in need of such treatment comprising or consisting of administering an amylin, an amylin agonist, or an amylin agonist analogue composition or compound in a defined amount, which amount is effective to treat obesity in the subject. Specifically, the invention contemplates the treatment of obesity in human subject in need of treatment by the administration of an amylin or amylin agonist. Indeed, Appellants discovered that amylin or amylin agonists can be used for the treatment of obesity.

Regarding the state of the prior art, obesity or adiposity as a chronic disease that is highly prevalent in modern society, which disease is strongly associated with multiple conditions including diabetes mellitus, insulin resistance, hypertension, etc. However, it was Appellants' discovery that amylin or amylin agonists could be administered to a human subject in need of treatment for obesity. In this respect, one of ordinary skill in the art would have the ability to select amylin and amylin agonist peptides for use in the claimed methods without undue experimentation. Indeed, amylin compounds recited in the claims are generally recognized as a defined class of compounds, and the specification provides ample direction and guidance to those skilled in the art with regard to the identification of such amylin compounds useful in the context of the claimed methods.

Regarding the relative skill of one of ordinary skill in the art, such skill is very high.

Regarding the predictability or unpredictability of the art, the Examiner alleges that the state of art with regard to the use of amylin is unpredictable. In this regard, the Examiner asserts (Final Office Action, page 14, line 27 to page 15, line 12) that both Baron *et al.* and Ratner *et al.* indicate the impracticability of using amylin as a therapeutic agent. Appellants disagree. Whether native human amylin is suitable for use as a commercial drug product is not a proper standard for judging the enablement of the present claims. Moreover, contrary to the Examiner's characterization of the cited references, it is submitted that both Baron *et al.* and Ratner *et al.* support enablement of the claimed invention. That is, given the teachings of the instant specification, one of ordinary skill in the art would have the ability to select amylin and amylin agonist peptides for use in the claimed methods without undue experimentation. This further

confirms that both amylin and amylin agonists are well known compounds that have been widely characterized. Given this, one of ordinary skill in the art would have the requisite skill to practice the invention commensurate in scope with the claims without undue experimentation.

Regarding the breadth of the claims, in rejecting the claims, the Examiner impermissibly attempts (e.g., Final Office Action page 9, lines 14-24) to limit the invention to the scope of the examples. Such a standard is legally incorrect. As set forth in MPEP § 2164.02, "[f]or a claimed genus, representative examples together with a statement applicable to the genus as a whole will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation." This is exactly what Appellants have provided. For example, Tables I-VII and Examples 1-3 disclose data relating to the claimed methods and exemplary amylin compounds. Alone, this disclosure is sufficient such that one of ordinary skill in the art at the time the invention was made would have the ability to practice the invention commensurate in scope with the claims.

The Examiner also comments on the scope of the claimed amylin compounds, and asserts (Final Office Action, page 12, lines 26-27) that "[t]he only amylin agonist analogue species or the peptide species that was administered in the instant invention was ... pramlintide." Appellants disagree. Again, the Examiner appears to be focusing impermissibly on the Examples rather than the teachings of the specification as a whole and the level of ordinary skill in the art. In this regard, it is noted that amylin and agonist thereof compounds recited in the claims are generally recognized as a defined class of compounds, and the specification provides ample direction and guidance to those skilled in the art with regard to the identification of such amylin compounds useful in the context of the claimed methods. Furthermore, the specification is replete with examples of amylin agonists, including functional variants, fragments, and derivatives of amylin and amylin agonists. See, e.g., Table VIII and page 15, line 1 to page 19, line 5. Accordingly, given at least the discussion in the background concerning amylin agonists, one of ordinary skill in the art having read the specification would have the ability to select known amylin agonists without undue experimentation. Moreover, to the extent that any additional experimentation may be required, Appellants note that the performance of routine and

well known steps cannot create undue experimentation even if it is laborious. See *In re Wands* (*Id.*); *In re Angstadt* (*Id.*).

Given the knowledge in the art, and based on the guidance provided in the specification regarding the extensive exemplary embodiments of amylin compounds, receptor binding assays and other assays for determining amylin activity, including the soleus muscle assay, and exemplary clinical study designs, additional therapeutically active amylin agonists can be identified within the context of the present claims without the need for undue experimentation. Based on such guidance, one of skill in the art would be able to practice the claimed invention with only routine experimentation.

Certain of the dependent claims recite specific types of amylin compounds. As generally understood by those of skill in the art, amylin analogues are compounds that are structurally related to the reference compound, i.e., amylin. As explained in the specification and understood by those skilled in the art, an amylin analogue can have one or more amino acid substitutions, deletions, inversions, or additions compared to a native or naturally occurring amylin. Furthermore, the claims clarify that the amylin analogue is an amylin agonist analogue. Thus, in accordance with the claims and the knowledge of those of ordinary skill in the art, the recited amylin agonist analogues are both structurally and functionally defined.

The Examiner also makes numerous comments with regard to the scope of various claim terms and transitional phrases. For instance, various claim terms such as obesity and administering are discussed in a broad context. While Appellants do not necessarily agree with the exact definition provided by the Examiner, Appellants do acknowledge the broad scope of such terms commensurate with the present specification. Furthermore, the Examiner comments on the claims use of traditional transitional phrases such as "comprising," "consisting of," and consisting essentially of'. In this regard, Appellants note that such language have been used in their traditional context. Thus, within the context of the claimed methods for treating obesity, such terms of art would have their traditional meanings and limitations with regard to claim elements relevant to the treatment of obesity. However, such traditional claim terms would have no bearing on components, steps, or elements outside of the claimed scope of the treatment of obesity.

The Examiner further asserts (Advisory Action, page 13, lines 22-25) that at the time of

the invention, amylin was administered to treat patients suffering from anorexia or patients deficient in adipose tissues. See Rink *et al.* (WO 92/20367) (hereinafter "Rink '367, already of record.) Thus, according to the Examiner (Advisory Action, page 14, lines 8-9), "one of skill in the art would have expected induction of weight gain..." Initially, the subject matter described in Rink '367 relates to anorexia and is therefore not germane to the current claims which require that a human subject be in need of treatment for obesity. That is, anorexic subjects are not in need of treatment for obesity. More generally, the Examiner selectively chooses exemplary disclosures relating to the historic appreciation of the action of amylin (and agonist thereof) without considering the full scope of the present disclosure. Indeed, it was Appellants' invention that amylin or amylin agonists could be useful in the treatment of obesity in a human subject in need of treatment for obesity.

Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection with respect to Claims 23, 24, 27, 29, 31-34, 37-39, 80, 82, 95 and 96.

Claim 68 is enabled

Arguments above for Claims 23, 24, 27, 29, 31-34, 37-39, 80, 82, 95 and 96 are reiterated. Additionally, Claim 68 requires that the amylin agonist analogue of Claim 24, from which Claims 68 depends, comprise a defined amino acid sequence, support for which may be found in the specification at, e.g., page 15, all lines. Indeed, amylin agonists according to Claim 68 is well known compounds that have been widely characterized, including use in treatment of obesity. Thus, Claim 68 is fully enabled, and Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection for Claim 68.

Claim 72 is enabled

Arguments above for 23, 24, 27, 29, 31-34, 37-39, 68, 80, 82, 95 and 96 are reiterated. Additionally, Claim 72 requires that the amylin agonist analogue of Claim 34, from which Claims 72 depends, comprise a defined amino acid sequence, support for which may be found in the specification at, e.g., page 15, all lines. Indeed, amylin agonists according to Claim 72 is well known compounds that have been widely characterized, including use in treatment of obesity.

Thus, Claim 72 is fully enabled, and Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection for Claim 72.

Claims 76, 84 and 97 are enabled

Arguments above for 23, 24, 27, 29, 31-34, 37-39, 68, 72, 80, 82, 95 and 96 are reiterated. Additionally, Claim 76 requires that the amylin agonist analogue thereof comprise a defined amino acid sequence, support for which may be found in the specification at, e.g., page 15, all lines. Indeed, amylin agonists according to Claim 76 is well known compounds that have been widely characterized, including use in treatment of obesity. Thus, Claim 76 and claims dependent therefrom are fully enabled, and Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection for Claims 76, 84 and 97.

5. Claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and 82 are not anticipated under 35 U.S.C. § 102(b) over Kolterman '220 as evidenced by Tsanev.

The rejection of Claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and 82 under 35 U.S.C. §102(b), (Final Office Action, page 20, item 26), for alleged anticipation over Kolterman '220 as evidenced by Tsanev, is in error for the reasons of record and the following reasons.

In order to anticipate a claim, a single prior art reference must provide each and every element set forth in the claim. *In re Bond*, 15 USPQ2d 1566, 1567 (Fed. Cir. 1990). See also, MPEP §2131. The identical invention must be shown in complete detail as it is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913 (Fed. Cir. 1989).

Claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and 82 *are not anticipated by the references*

Arguments set forth for above Rejection 1 are reiterated. Claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and 82 are directed *inter alia* to methods of treating obesity in a human subject in need of such treatment through administration of a defined amount of an amylin or an amylin agonist. In contrast, as acknowledged by the Examiner (Final Office Action, page 21, lines 12-21), Kolterman '220 describes the use of an amylin agonist (i.e., pramlintide) for treating type II diabetes mellitus. Indeed, Kolterman '220 merely demonstrates that administration of an amylin agonist significantly reduces postprandial plasma glucose concentrations in patients with type II

diabetes mellitus. In particular, Kolterman '220 does not teach the use of an amylin or an amylin agonist for treating obesity or demonstrate a reduction in body weight in those patients administered an amylin or an amylin agonist. Indeed, Kolterman '220 is silent with regard to the effect of an amylin or an amylin agonist on body weight.

The Examiner asserts (Final Office Action, page 21, line 22-25) that "Kolterman et al. ('220) taught the benefit of obtaining weight loss in Type II diabetic patients by teaching that hyperglycemia associated with Type II diabetes can be reversed or ameliorated by weight loss sufficient to restore the sensitivity of the peripheral tissues to insulin (see pages 7, first paragraph), ..." However, a careful reading of Kolterman '220 at page 7, first paragraph, discloses that "the hyperglycemia associated with Type II diabetes can sometimes be reserved or ameliorated by diet or weight loss... (*emphasis added*)." In any event, with respect to the use of amylin or amylin agonists for treatment of obesity in a subject in need thereof, Kolterman '220 is silent. Accordingly, whether or not Kolterman '220 discloses that weight loss is beneficial is irrelevant, at least because the Examiner has failed to provide a nexus within Kolterman '220 (with or without evidence by Tsanev as described below) between administration of an amylin or agonist thereof and treatment for obesity. Indeed, it was Appellants discovery that amylin or agonists thereof are useful for treating obesity in human subjects in need of treatment thereof.

In an attempt to cure the deficiency in Kolterman '220, the Examiner relies on Tsanev to allegedly provide evidence that 80-90% of diabetic patients are obese. The crux of the Examiner's argument appears to be (Final Office Action, page 22, lines 5-11) that "[g]iven Tsanev's express dislcosure ..., and given Kolterman's ('220) express recognition that obesity is a characterist of 'most patients with Type II diabetes mellitus' and the indication that these patients are in need of weight loss, Kolterman's ('220) method of subcutaneous administration of pramlintide to at least one Type II diabetic patient... necessarily serves as the claimed method of treating obesity and therefore anticipates the instantly claimed method (*emphasis added*)."

However, the 80-90% of obese diabetic patients alleged by Tsanev falls short of the 100% (i.e., always, under any circumstances) criterion required by the claims and required by the law as discussed in the response to above Rejection 1. See e.g., *Schering Corp. v. Geneva Pharms., Inc., Id.*; *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc., Id.*) Thus, Kolterman '220 as evidenced by Tsanev does not provide each and every element of the claimed invention,

at least because Kolterman '220 (with or without Tsanev) is silent with respect to treatment of obesity with amylin or agonists thereof, or the intended population for treatment (i.e., human subject in need of treatment for obesity). Accordingly, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

6. Claims 23, 24, 29, 33, 34 and 38 are not anticipated under 35 U.S.C. § 102(e)(2) over Gaeta as evidenced by Tsanev.

The rejection of Claims 23, 24, 29, 33, 34 and 38 under 35 U.S.C. §102(e)(2) (Final Office Action, page 24, item 27), for alleged anticipation over Gaeta as evidenced by Tsanev, is in error for the reasons of record and the following reasons.

Claims 23, 224, 29, 33, 34 and 38 are not anticipated by the references

Arguments set forth for above Rejection 1 are reiterated. In summary, Gaeta is silent with respect to treating obesity, nothing in Gaeta teaches or suggests the use of an amylin or an amylin agonist in an amount effective to treat obesity, and nothing in Gaeta teaches or suggests the identification of or intent to treat a subject in need of treatment for obesity.

In an attempt to cure the deficiency of Gaeta, the Examiner relies on Tsanev to provide alleged evidence that 80-90% of diabetic patients are obese. Indeed, the Examiner asserts (Final Office Action, page 26, lines 10-13) that '... Tsanev is not used as a secondary reference in combination with the reference of Gaeta et al. ('411), but rather is used to show that every element of the claimed subject matter is disclosed by Gaeta et al. ('411) with the unrecited limitation(s) being inherent as evidenced by the state of the art (*emphasis added*)." However, the law is clear that anticipation based on inherency is appropriate only when the prior art relied upon necessarily includes all of the elements of the claims in question, *Atofina v. Great Lakes Chemical Corp.* (*Id.*), and is the natural result of following the instructions or examples of the prior art. See *SmithKline Beecham Corp. v. Apotex Corp.*, (*Id.*) In the present case, 80-90% falls short of the 100% (i.e., always, under any circumstances) criterion required by the claims and required by the law. Accordingly, Gaeta does not anticipate the claimed invention, and Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

7. Claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and 82 are not anticipated under 35

U.S.C. § 102(b) over Kolterman 1996 as evidenced by Itasaka.

The rejection of Claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and 82 under 35 U.S.C. §102(b), (Final Office Action, page 27, item 28), for alleged anticipation by Kolterman 1996 as evidenced by Itasaka, is in error for the reasons of record and the following reasons.

Claims 23, 24, 27, 29, 31, 33, 34, 37-39, 80 and 82 are not anticipated by the references

Arguments set forth for Rejection 1 are reiterated. Subject matter contemplated by the rejected claims has been described (*supra*). In contrast to the present claims, Kolterman 1996 merely describes the use of an amylin agonist (pramlintide) for treating patients with insulin-dependent diabetes mellitus and demonstrates *inter alia* that administration of the amylin agonist significantly reduces postprandial plasma glucose concentrations. However, Kolterman 1996 discloses neither the use of the amylin agonist for treating obesity nor a reduction in body weight in those patients administered the amylin agonist. Indeed, Kolterman 1996 does not report the weight of the subjects at the end of the study and nothing in the reference indicates that pramlintide had any effect on the weight of the subjects. Accordingly, Kolterman 1996 is silent with regard to the effect of the amylin agonist on body weight.

In an effort to cure the deficiencies of Kolterman 1996, the Examiner relies on Itasaka to allegedly provide a correlation between body mass index (BMI) and obesity. Appellants disagree with the Examiner assertion (Final Office Action, page 28, lines 26-27) that "the very active step recited in the instantly claimed method was disclosed and practiced by Kolterman et al. in April, 1996." The patient population of Kolterman 1996 is not necessarily the same as the claimed subject, *i.e.*, a subject in need of treatment for obesity. The Examiner has provided no evidence to show that these patient populations are identically one in the same. Accordingly, the "fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic." *In re Rijckaert*, 9 F.3d 1531, 1534 (Fed. Cir. 1993). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the references, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " *In re Robertson* 169 F.3d 743, 745 (Fed. Cir. 1999). Furthermore, the courts have held that the phrase "in need thereof" recited in the claims is

meaningful. See *Jansen v. Rexall Sundown, Inc.* (*Id.*). Thus, Kolterman 1996 cannot render unpatentable by inherency the subject population of the claimed invention, with or without Itasaka. Because Kolterman 1996 as evidenced by Itasaka does not teach every element of the claims of the present invention, Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

8. Claims 23, 24, 27, 29, 33, 34, 37 and 38 are not anticipated under 35 U.S.C. § 102(e)(2) over Beaumont as evidenced by Tsanev.

The rejection of Claims 23, 24, 27, 29, 33, 34, 37 and 38 under 35 U.S.C. §102(e)(2), (Final Office Action, page 30, item 29), for alleged anticipation over Beaumont as evidenced by Tsanev, is in error for the reasons of record and the following reasons.

Claims 23, 24, 27, 29, 33, 34, 37 and 38 are not anticipated by the references

The arguments set forth for Rejections 1-2 are reiterated. In contrast to the current claims, and as acknowledged by the Examiner (Office Action, page 25, lines 5-8), Beaumont describes "a method of subcutaneous administration to an insulin-requiring human who suffers from Type 1 or Type 2 diabetes mellitus a therapeutically effective amount of an amylin agonist alone such as calcitonin, or calcitonin and insulin, contained in a pharmaceutically acceptable carrier." Beaumont is silent with respect to obesity, treatment of obesity, or intent to treat a human subject in need of treatment for obesity.

In an attempt to cure the deficiency of Beaumont, the Examiner relies on Tsanev to provide alleged evidence that 80-90% of diabetic patients are obese. However, 80-90% falls short of the 100% (i.e., always, under any circumstances) criterion required by the claims and required by the law as discussed in the response to above Rejections 1-2. See e.g., *Schering Corp. v. Geneva Pharms., Inc.*, *Id.*; *Abbott Laboratories v. Baxter Pharmaceutical Products, Inc.*, *Id.*) Thus, Beaumont patent does not provide each and every element of the claimed invention. Appellants request that the Board remand the application to the Examiner with instructions to remove the current rejection.

Conclusion

The above discussion is fully responsive to all grounds of rejection set forth for the application. In view of the foregoing, it is requested that the Board of Patent Appeals and Interferences remand the application to the Examiner with instructions to remove all rejections and to issue a Notice of Allowance.

Appellants believe that no additional fees are due for the present submission. The Commissioner is hereby authorized to charge payment for any outstanding fees set forth in 37 C.F.R. § 1.136, 37 C.F.R. § 1.17 and/or 37 C.F.R. § 41.20 due for this Appeal Brief to Appellants' Deposit Account No. 010535 referencing Atty. Dkt. No. 235/013 US. In the event that an extension of time is required under 37 C.F.R. § 1.136, Appellants hereby petition for such extension of time and authorize the Commissioner to charge the requisite fee to Appellant's Deposit Account No. 010535. Additionally, the Commissioner is hereby authorized to charge payment or credit overpayment of any fees during the pendency of this application to Appellant's Deposit Account No. 010535.

Date: October 29, 2008

Respectfully submitted,
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Appendix A: Claims Appendix

23. (Previously presented) A method of treating obesity in a human subject comprising administering to said subject an amount of a composition comprising an amylin or amylin agonist effective to treat obesity in said human subject, wherein the amount of the amylin or amylin agonist administered in said composition is about 0.01 mg to about 5 mg per day, wherein said composition is not administered in conjunction with another obesity relief agent, and wherein said human subject is in need of treatment for obesity.

24. (Previously presented) The method according to claim 23 wherein said amylin agonist is an amylin agonist analogue.

27. (Previously presented) The method according to claim 23 wherein said composition is administered subcutaneously.

29. (Previously presented) The method according to claim 23 wherein said composition is administered from 1 to 4 times per day.

31. (Previously presented) The method according to claim 23 wherein said composition is administered before a meal.

32. (Previously presented) The method according to claim 23 wherein said composition is administered within about 15 minutes of a meal.

33. (Previously presented) A method of treating obesity in a human subject, said method consisting of administering to said subject an amount of a composition effective to treat obesity in said human subject, said composition comprising an obesity relief agent consisting of an amylin or an amylin agonist and a pharmaceutically acceptable carrier, wherein the amount of said amylin or amylin agonist administered in said composition is about 0.01 mg to about 5 mg per day, and wherein said human subject is in need of treatment for obesity.

34. (Previously presented) The method according to claim 33 wherein said amylin agonist is an amylin agonist analogue.

37. (Previously presented) The method according to claim 33 wherein said composition is administered subcutaneously.

38. (Previously presented) The method according to claim 33 wherein said composition is administered from 1 to 4 times per day.

39. (Previously presented) The method according to claim 33 wherein said composition is administered before a meal.

68. (Previously presented) The method according to claim 24, wherein the amylin agonist analogue comprises an amino acid sequence of:

$^{1}A_1$-X-Asn-Thr-^{5}Ala-Thr-Y-Ala-Thr^{10}Gln-Arg-Leu-B_1-Asn-^{15}Phe-Leu-C_1-D_1-E_1-$^{10}F_1$-G_1-Asn-H_1-Gly-^{25}Pro-I_1-Leu-Pro-J_1-^{30}Thr-K_1-Val-Gly-Ser-^{35}Asn-Thr-Tyr-Z (SEQ ID NO:14)

wherein

A_1 is Lys, Ala, Ser or hydrogen;

B_1 is Ala, Ser or Thr;

C_1 is Val, Leu or Ile;

D_1 is His or Arg;

E_1 is Ser or Thr;

F_1 is Ser, Thr, Gln or Asn;

G_1 is Asn, Gln or His;

H_1 is Phe, Leu or Tyr;

I_1 is Ile, Val, Ala or Leu

J_1 is Ser, Pro or Thr;

K_1 is Asn, Asp or Gln;

X and Y are independently selected residues having side chains which are chemically bonded to each other to form an intramolecular linkage, wherein said intramolecular linkage comprises a disulfide bond, a lactam or a thioether linkage; and Z is an amino, alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy; and provided that when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Val, J_1 is Pro, and K_1 is Asn; then one or more A_1 to K_1 is a D-amino acid and Z is

selected from the group consisting of alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy.

72. (Previously presented) The method according to claim 34, wherein the amylin agonist analogue comprises an amino acid sequence of:

$^{1}A_1$-X-Asn-Thr-^{5}Ala-Thr-Y-Ala-Thr^{10}Gln-Arg-Leu-B_1-Asn-^{15}Phe-Leu-C_1-D_1-E_1-$^{10}F_1$-G_1-Asn-H_1-Gly-^{25}Pro-I_1-Leu-Pro-J_1-^{30}Thr-K_1-Val-Gly-Ser-^{35}Asn-Thr-Tyr-Z (SEQ ID NO:14)

wherein

A_1 is Lys, Ala, Ser or hydrogen;

B_1 is Ala, Ser or Thr;

C_1 is Val, Leu or Ile;

D_1 is His or Arg;

E_1 is Ser or Thr;

F_1 is Ser, Thr, Gln or Asn;

G_1 is Asn, Gln or His;

H_1 is Phe, Leu or Tyr;

I_1 is Ile, Val, Ala or Leu

J_1 is Ser, Pro or Thr;

K_1 is Asn, Asp or Gln;

X and Y are independently selected residues having side chains which are chemically bonded to each other to form an intramolecular linkage, wherein said intramolecular linkage comprises a disulfide bond, a lactam or a thioether linkage; and Z is an amino, alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy; and provided that when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Val, J_1 is Pro, and K_1 is Asn; then one or more A_1 to K_1 is a D-amino acid and Z is selected from the group consisting of alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy.

76. (Previously presented) A method of treating obesity in a human subject comprising

administering to said subject an amount of a composition effective to treat obesity in said human subject, wherein said human subject is in need of treatment for obesity, said composition comprising a peptide having an amino acid sequence of:

$^{1}A_1$-X-Asn-Thr-^{5}Ala-Thr-Y-Ala-Thr^{10}Gln-Arg-Leu-B_1-Asn-^{15}Phe-Leu-C_1-D_1-E_1-$^{10}F_1$-G_1-Asn-H_1-Gly-^{25}Pro-I_1-Leu-Pro-J_1-^{30}Thr-K_1-Val-Gly-Ser-^{35}Asn-Thr-Tyr-Z (SEQ ID NO:14)

wherein

A_1 is Lys, Ala, Ser or hydrogen;

B_1 is Ala, Ser or Thr;

C_1 is Val, Leu or Ile;

D_1 is His or Arg;

E_1 is Ser or Thr;

F_1 is Ser, Thr, Gln or Asn;

G_1 is Asn, Gln or His;

H_1 is Phe, Leu or Tyr;

I_1 is Ile, Val, Ala or Leu

J_1 is Ser, Pro or Thr;

K_1 is Asn, Asp or Gln;

X and Y are independently selected residues having side chains which are chemically bonded to each other to form an intramolecular linkage, wherein said intramolecular linkage comprises a disulfide bond, a lactam or a thioether linkage; and Z is an amino, alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy; and provided that when A_1 is Lys, B_1 is Ala, C_1 is Val, D_1 is Arg, E_1 is Ser, F_1 is Ser, G_1 is Asn, H_1 is Leu, I_1 is Val, J_1 is Pro, and K_1 is Asn; then one or more A_1 to K_1 is a D-amino acid and Z is selected from the group consisting of alkylamino, dialkylamino, cycloalkylamino, arylamino, aralkylamino, alkyloxy, aryloxy or aralkyloxy, wherein said amount is effective to treat obesity and wherein said composition is not administered in conjunction with another obesity relief agent.

80. (Previously presented) The method according to claim 23 wherein the amount of the amylin or amylin agonist administered is from about 30 μg/dose to about 300 μg/dose.

82. (Previously presented) The method according to claim 33 wherein said amylin or amylin agonist is administered at a dose from about 30 μg/dose to about 300 μg/dose.

84. (Previously presented) The method according to claim 76 wherein said peptide is administered at a dose from about 30 μg/dose to about 300 μg/dose.

95. (Previously presented) The method according to claim 23 wherein said subject has a body mass index of at least 27.0 kg/m^2.

96. (Previously presented) The method according to claim 33 wherein said subject has a body mass index of at least 27.0 kg/m^2.

97. (Previously presented) The method according to claim 76 wherein said subject has a body mass index of at least 27.0 kg/m^2.

Appendix B: Evidence Appendix

None.

Appendix C: Related Proceedings Appendix

None.